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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,705

03/30/2004

J. Richard Gyory

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07/21/2006

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,705	<b>Applicant(s)</b> GYORY, J. RICHARD	
	<b>Examiner</b> Andrew M. Gilbert	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 5/10/2006.
2. In the reply, the applicant amended claims 1 and 6 and added new claims 7-16.
3. Additionally, the applicant submitted Figure 1 in a replacement sheet to label Figure 1 as "Prior Art" and accordingly the objection is withdrawn.
4. The applicant submitted a new drawing sheet for Figure 5. The submission of new Figure 5 is objected to as being new matter (see discussion below).

### ***Specification***

5. The amendment filed 5/10/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The submission of newly added Figure 5 showing the device depicted in Figure 4, as well as a second set of the elements depicted in Figure 4, including a first reservoir containing an active agent formulation, a second reservoir containing a biocompatible electrolyte formulation, and a power source introduces new matter into the disclosure because nowhere in the specification as originally filed, including original claim 1, does the applicant sufficiently describe their invention so as to produce Figure 5. The introduction of Figure 5 introduces new matter because via Figure 5 the applicant can now seek to claim, for instance, that the power source is located on the topside of the circuit board or that the flexible region (105) is shaped in a U-shape.

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6. Additionally, the submission of new paragraph (Amendments to the Specification, pg 3, paragraph 3) following paragraph 31 is added material not supported by the original disclosure because the paragraph describes the invention having a second flexible conductor with an electrode coating on the electrode end that is in contact with an electrolyte reservoir.

7. The Examiner notes that the only submission as an Amendment to the Specification that would not be regarded as new matter is an exact word for word copy of claim 1 as originally filed. That is the only subject matter of the claimed invention the applicant had possession of at the time the application was filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed subject matter of the Applicant's invention having a second reservoir, a second electrode, and an electrolyte formulation. While the applicant notes that the Background of the Specification discusses a second reservoir, a second electrode, and a electrolyte formulation as being well known and common in the

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art at the time of invention, the Applicant at no point mentions that their invention has a second reservoir, a second electrode, or an electrolyte formulation except in originally filed claim 1.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Linkwitz et al (6295469). Linkwitz et al discloses an electrotransport device (70) having a first (72) and second (73) electrode, the first electrode in communication with a first reservoir (82) adapted to receive an active agent formulation that is a therapeutic agent (col 3, ln 43-col 5, ln 21), the second electrode in communication with a second reservoir (86) adapted to receive an electrolyte formulation (col 10, lns 33-34), a power source (90) in communication with electronic circuitry (91) in communication with first and second electrodes (Fig 4), a non-conductive reservoir housing (81) having an internal cavity (Fig 4; col 10, lns 29-30) containing said first electrode (72) and first reservoir (82) and the reservoir housing having an electrically conductive element (72, 75) integrally molded within the non-conductive housing and that is substantially planar (Fig 3, Fig 4), flexible (75; Fig 2, Fig 3), with a conductive coating (col 9, ln 66- col 10, ln 27; Fig 5) and that has a first end in communication with the first reservoir (Fig 4; col 9, lns 48-50) and a

second end that is disposed on the outside of the reservoir housing (81) and extending therefrom to be operatively connected to the power source through the electronic circuitry (Fig 4; col 9, lns 43-50).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linkwitz et al. Linkwitz et al discloses the invention substantially as claimed except for expressly disclosing wherein the active agent formulation includes a therapeutic agent being the specific agents disclosed in the applicant's claims 7-16. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the therapeutic agent being the specific agents disclosed in the applicant's claims 7-16 because the Applicant has not disclosed that having the therapeutic agent being the specific agents disclosed in the applicant's claims 7-16 provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with therapeutic agents of Linkwitz et al because the Applicant has not given any criticality for the therapeutic agents being the specifically claimed agents. Therefore, it would have been an obvious matter of design choice to modify Linkwitz et al to obtain the invention as specified in claims 7-16.

***Response to Arguments***

13. Applicant's arguments filed 5/10/2006 have been fully considered but they are not persuasive.

14. The applicant argues that Linkwitz does not have (i) a non-conductive reservoir housing having an internal cavity containing the first electrode and said first reservoir; (ii) an electrically conductive element integrally molded within the non-conductive housing; and (iii) an electrically conductive element with a second end that is on the outside of a non-conductive reservoir housing and that extends from the housing.

15. In response to applicant's argument (i) the Examiner notes that Linkwitz does have a non-conductive reservoir housing (81) being a foam layer that has a centrally position cavity holding the donor reservoir (82). The centrally positioned cavity does in fact enclose and contain an electrode (see 72, 74; col 10, lns 28-34)).

16. In response to applicant's argument (ii) the Examiner notes that Linkwitz does have a non-conductive reservoir housing (81) being a foam layer that has a centrally position cavity holding the donor reservoir (82) and an electrically conductive element (72) integrally molded within the non-conductive housing (Fig 4). Wherein the Examiner notes that the electrically conductive element is integrally molded to the non-conductive housing and that a portion of the electrically conductive element (72) does reside within and contact the centrally positioned cavity of the housing (72, 81, 82, 74; Fig 4).

17. In response to applicant's argument (iii) the Examiner notes that Linkwitz does have an electrically conductive element (72) with a second end (75) that is on the

outside of a non-conductive reservoir housing (81) and that extends from the housing (Fig 4; col 9, lns 43-50).

18. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a non-conductive housing that covers a donor reservoir and electrode; it appears the Applicant is intending to argue that Linkwitz does not have a non-conductive housing that cavity that encompasses the entire donor reservoir and electrode; yet these limitations are not in the claims) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



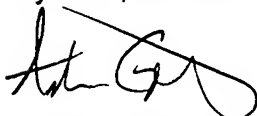
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300..

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

